



K121883
p1/2

510(k) SUMMARY
Prevena Incision Management System
with Customizable Dressing

OCT 11 2012

| | | |
|---|---|---|
| Submitter Information [21 CFR 807.929(a)(1)] | | |
| Name | KCI USA, Inc. (Kinetic Concepts, Inc.) | |
| Address | 6203 Farinon Drive San Antonio, TX 78249 | |
| Phone number | 210-515-4368 | |
| Fax number | 210-255-6727 | |
| Establishment Registration Number | 1625774 | |
| Name of contact person | Shannon Scott, Regulatory Affairs Senior Manager | |
| Date prepared | June 26, 2012 | |
| Name of the device [21 CFR 807.92(a)(2)] | | |
| Trade or proprietary name | Prevena Incision Management System with Customizable Dressing | |
| Common or usual name | Negative Pressure Wound Therapy System | |
| Classification name | Negative Pressure Wound Therapy Powered Suction Pump (and components) | |
| Classification panel | General and Plastic Surgery | |
| Regulation | 878.4780 | |
| Product Code(s) | OMP | |
| Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)] | Prevena Incision Management System (K100821) | |
| Device description [21 CFR 807.92(a)(4)] | Negative pressure wound therapy system for application to surgically closed incisions. | |
| Indications for use [21 CFR 807.92(a)(5)] | The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy. | |
| Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)] | | |
| The subject device was found to be equivalent to the predicate device in delivery of negative pressure to the indicated wound type. The devices are equivalent in terms of functional components. | | |
| Characteristic | New Device <i>Prevena™ Incision Management System with Customizable Dressing</i> | Predicate <i>Prevena™ Incision Management System with Peel and Place Dressing K100821</i> |
| Indicated wound types | Same as predicate | Closed surgical incisions |
| Dressing | Multiple dressing components | Single, one size, multi-layer dressing. |



K121883
p 2/2

| | | |
|--|-------------------|--|
| Therapy unit | Same as predicate | Single patient use only; battery powered |
| Performance Data [21 CFR 807.92(b)] | | |
| Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)] | | |
| <p>The Prevena Incision Management System with Customizable Dressing was evaluated under a number of design verification and validation tests to assure safety, efficacy, conformance to design specifications and equivalence to the predicate device. The following tests were conducted:</p> <ul style="list-style-type: none">• Biocompatibility testing according to ISO 10993-1• Equivalency testing of the Prevena Customizable Dressing to the Prevena Peel and Place Dressing with respect to delivery of negative pressure wound therapy• Software verification and validation testing | | |
| Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)] | | |
| Clinical tests were conducted to demonstrate substantial equivalence with regard to device performance. | | |
| Conclusions drawn [21 CFR 807.92(b)(3)] | | |
| Testing demonstrates that the Prevena Incision Management System with Customizable Dressing and the Prevena Incision Management System with Peel and Place Dressing are substantially equivalent in terms of both indications for use and delivered wound therapy. | | |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

OCT 11 2012

Kinetic Concepts USA, Incorporated
% Ms. Shannon Scott
Regulatory Affairs Senior Manager
6203 Farinon Drive
San Antonio, Texas 78249

Re: K121883

Trade/Device Name: Prevena Incision Management System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 7, 2012
Received: September 10, 2012

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

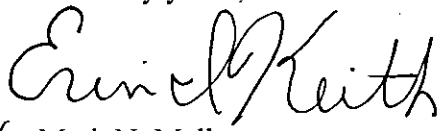
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121883

INDICATIONS FOR USE

510(k) Number (if known): K121883

Device Name: Prevena Incision Management System

Indications for Use:

The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krane

(Division Sign-Off)

Page 1 of 1

(Posted November 13, 2003)

Division of Surgical, Orthopedic,
and Restorative Devices

311

510(k) Number K121883